IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

07-2467

UNITED STATES, ex rel.

ELAINE GEORGE,
607 Southern Hills Drive
Eureka, MO 63025

BRINGING THIS ACTION
ON BEHALF OF THE UNITED
STATES OF AMERICA,
c/o Patrick J. Fitzgerald
United States Attorney
for the Northern District of Illinois
219 S. Dearborn St., 5th Floor
Chicago, IL 60604

-and-

c/o Alberto R. Gonzales, Esquire
Attorney General of the United States
Department of Justice
10th and Constitution Ave., N.W.
Washington, D.C. 20530

Plaintiffs,

v.

BOSTON SCIENTIFIC CORPORATION,

and

GUIDANT CORPORATION,

Defendants.

06CV6141
JUDGE HOLDERMAN
MAG.JUDGE NOLAN

COMPLAINT FOR
VIOLATIONS OF
FEDERAL FALSE
CLAIMS ACT

JURY TRIAL DEMAND

FILED UNDER SEAL

FILED
NOV - 9 2006
MICHAEL W. DOBBINS
CLERK, U.S. DISTRICT COURT

I. INTRODUCTION AND OVERVIEW OF BOSTON SCIENTIFIC CORPORATION'S FRAUDULENT CONDUCT

1. Elaine George (hereinafter "Relator") brings this qui tam action on behalf of the United States to recover upwards of tens of millions of dollars of losses sustained by Medicare as a result of the ongoing efforts of Boston Scientific Corp. ("Boston Scientific") and Guidant Corp. ("Guidant") (collectively hereinafter "Defendants") to defraud Medicare by causing the submission of false and excessively over-priced Medicare claims for the off-label use of Defendants' microwave ablation system to treat atrial fibrillation.

2. The fraudulent conduct includes: (1) soliciting and inducing doctors and hospitals to submit an incorrect procedural code to Medicare, which results in an overcharge to the Government of as much as $21,765 per "stand-alone-use" of Defendants' microwave ablation system, which is 355% higher than the reimbursement amount which Medicare should be paying for such minimally invasive procedures; (2) soliciting and inducing doctors and hospitals to use the microwave surgical ablation system off-label to treat atrial fibrillation by offering them higher monetary reimbursements from Medicare, even though Defendants have been *denied* approval to use this system to treat atrial fibrillation; (3) reimbursing hospitals with kick-backs and remunerations such as rebates, lower prices, and free products, the proceeds of which are not reported or provided to Medicare, when the hospital agrees to purchase a targeted quantity of the microwave ablation system to treat atrial fibrillation; (4) training doctors to use the microwave ablation system for the off-label use of treating atrial fibrillation; and (5) requiring sales

representatives to accompany doctors into the operating room to help them administer the microwave ablation system off-label to treat Medicare patients with atrial fibrillation.

3. This action is brought pursuant to the False Claims Act, 31 U.S.C. §§ 3729 et. seq.

4. The False Claims Act ("Act") provides, inter alia, that any person who knowingly presents, or causes to be presented, a false or fraudulent claim paid or approved by the Government is subject to liability. The Act also holds liable any person who conspires to defraud the Government by getting a false or fraudulent claim allowed or paid and any person who knowingly makes, uses, or causes to be made or used, a false record or statement to cause a false claim to be approved or to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government. A civil penalty of up to $11,000.00 is imposed for each claim, plus three times the amount of the damages sustained by the government, including attorneys' fees. The Act allows any person having information regarding a false or fraudulent claim against the Government to bring a private cause of action for himself and on behalf of the Government and to share in any recovery. The complaint is to be filed under seal for 60 days (without service on the Defendants during such 60-day period) to enable the Government (a) to conduct its own investigations without the Defendants' knowledge, and (b) to determine whether to join the action. Suits brought under the Act may include false claims made within six years of the date of filing.

5. Based on the provisions of the False Claims Act, Relator, Elaine George, seeks to recover damages and civil penalties arising from Defendants' presentation of false claims

to the United States Government to obtain Medicare compensation for the off-label use of the microwave ablation system to treat atrial fibrillation.

II. PARTIES

6. Elaine George is a resident of Saint Louis County, Missouri. Ms. George was employed by Boston Scientific from June 12, 2006 to September 28, 2006 as a Sales Representative in the Midwest region and worked in both Belleville, Illinois and St. Louis.

7. Defendant Boston Scientific Corporation is headquartered in Natick, Massachusetts. Boston Scientific develops, manufactures and markets medical devices. On April 21, 2006, Boston Scientific acquired Guidant Corporation, subsuming Guidant's Cardiac Rhythm Management and Cardiac Surgery units. Boston Scientific has been violating the False Claims Act by causing the submission of fraudulent Medicare claims for the off-label use of the microwave surgical ablation system to treat atrial fibrillation.

8. Defendant Guidant Corporation is headquartered in Indianapolis, Indiana. Guidant designs, develops and markets cardiovascular medical products, including the Flex 4, 10, and Flexview Microwave Surgical Ablation System. On April 21, 2006, Guidant's Cardiac Rhythm Management and Cardiac Surgery units became a part of Boston Scientific, and Guidant's vascular and endovascular businesses became a part of Abbott Vascular. Guidant has been violating the False Claims Act by causing the submission of Medicare claims for the off-label use of its microwave surgical ablation system to treat atrial fibrillation.

III. JURISDICTION AND VENUE

9. This court has jurisdiction over the subject matter of the action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, which confer jurisdiction in the Court of actions brought pursuant to Title 31 sections 3729 and 3730.

10. This action is not based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the government is already a party nor upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media. Moreover, Relator has direct and independent knowledge of the information on which the allegations of this lawsuit are based. Relator is thus an original source of the information on which the allegations of this lawsuit are based.

11. Venue under the False Claims Act is proper in any judicial district in which the defendant can be found, resides, transacts business, or in which any false or fraudulent act proscribed by section 3729 occurred. 31 U.S.C. § 3732(a). Because Boston Scientific transacts business in the Northern District of Illinois, venue in this district is proper.

IV. BACKGROUND AS TO HOW THE GOVERNMENT PAYS MEDICARE CLAIMS WHEN MEDICAL DEVICES ARE USED TO TREAT A "MEDICALLY ACCEPTED INDICATION"

12. Pursuant to governmental medical reimbursement systems such as Medicare, the U.S. government only pays claims for the use of a medical device if (1) a rendering healthcare provider submits a claim for reimbursement on an appropriate claim form, and

(2) the claim form is completed and the information provided on the form, if true, would make the claim eligible for reimbursement.

13. To obtain such payments, the healthcare provider must certify that the services it rendered to a patient "were medically indicated and necessary." *See* 42 U.S.C. § 1320c-5(a); *see also* Exhibit 1, p. 1.

14. The signature of the healthcare provider on government claim forms, such as Medicare claim forms, constitutes the provider's certification that the services rendered "were medically indicated and necessary." *See* Exhibit 1, p.1 (requiring signature of physician or supplier on HCFA-1500 form, which is a form used for billing Medicare).

15. The healthcare provider's certification that the services rendered "were medically indicated and necessary" in turn constitutes its certification that the claim is eligible for reimbursement under federal law. *See* Exhibit 1, p. 1.

16. To be eligible for reimbursement under governmental medical reimbursement systems such as Medicare, a medical device must be used for a "medically accepted indication." *See* Exhibit 1, p. 1.

17. A "medically accepted indication" is one that is either approved by the FDA or listed in certain medical compendia. 42 U.S.C.A. § 1396r-8(k)(6). Use of a medical device for any condition that is not a "medically accepted indication" is referred to hereinafter as an "off-label" use.

18. When health care providers submit claims for Medicare reimbursement, the use of correct codes is critical to determine whether or not a treatment is covered by Medicare and the extent of coverage. The correct procedural code must be selected by health care providers and listed on all Medicare billing forms as a standardized International

Classification of Diseases, Ninth Edition, Clinical Modification ("ICD-9") number. Correct ICD-9 codes are vital to proper reimbursement.

19. When governmental medical reimbursement systems such as Medicare provide compensation for claims submitted, they rely upon the certification of hospitals and physicians that (1) the information and ICD-9 codes provided are accurate, and (2) that the hospitals and physicians exercised unbiased professional medical judgment when deeming a service "medically indicated and necessary."

20. Pursuant to the Medicare-Medicaid Antifraud and Abuse Amendments, 42 U.S.C. § 1320a-7b, it is illegal for pharmaceutical companies to make payments to induce or reward healthcare providers for referring, recommending or arranging for federally-funded medical items provided under the Medicare program.

21. It is illegal for pharmaceutical companies to knowingly and willfully offer or pay any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to induce a health care provider to purchase or order products that will be paid for in whole or in part under Medicare. 42 U.S.C. § 1320a-7b.

22. Most rebates and discounts on Medicare-reimbursed items violate the Medicare-Medicaid Antifraud and Abuse Amendments. However, if the rebate or discount is properly reported and the proceeds are appropriately passed on to Medicare, it may fall within a ""safe harbor" of protected activity. *See* 42 U.S.C. § 1320a-7b(b)(3)(A).

V. FACTUAL ALLEGATIONS

A. The Microwave Surgical Ablation System

23. Defendants' surgical ablation system consists of a microwave generator and a surgical ablation probe that delivers a continuous flow of microwave energy from the generator to the cardiac tissue. The system is designed to ablate tissue by the induction of cell death in the targeted areas. *See* Exhibit 8.

24. Defendants' microwave surgical ablation system can be used either in conjunction with open heart surgery or as a stand-alone, minimally invasive, procedure. *See* Exhibit 2, p. 3 ("Microwave surgical ablation can be performed in combination with valve or coronary bypass surgeries or in minimally invasive, stand-alone procedures."); *see also* Exhibit 6, p. 29; Exhibit 9, p. 176.

25. A stand-alone minimally invasive, procedure, unlike traditional heart surgery, does not require opening the thoracic cavity to expose the heart and lungs and does not require a heart-lung machine. *See* Exhibit 2, p. 1; *see also* Exhibit 2, p. 3 (describing that by using the minimally invasive, closed-chest, procedure, patients "should recover faster and with less pain than with procedures that require rib spreading.")

26. During the stand-alone, minimally invasive, microwave surgical ablation procedure, the surgeon usually will make small incisions called ports in the chest. Typically, there are up to six ports in total (1/2" to 3/4" in size). Using an endoscope—a tiny camera that can be inserted into the ports—the surgeon is able to view the heart without having to open the chest cavity. The surgeon will then insert special instruments through the ports to perform the procedure, including the endoscope, small scissors, and graspers. These tools will help the surgeon move the Guidant FLEX Probe—a narrow,

flexible device—into position to burn the lesion sets onto the surface of the heart. Lesions are necessary to stop the occurrence of atrial fibrillation. Using the Probe, the surgeon will then deliver targeted amounts of microwave energy to the heart. The entire procedure usually takes about, on average, three hours to complete. *See* Exhibit. 2, p. 1.

27. Defendants' microwave surgical ablation system is categorized as a Class II device, which pursuant to 42 C.F.R. 405.201 "require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness." Exhibit 3, p. 1.

28. The indicated use of microwave surgical ablation that was cleared by the FDA in Defendants' 510(k) premarket notification was for *general use* in "the surgical ablation of soft tissue, and striated, cardiac, and smooth muscle." Exhibit 3, p. 5. The system is a device "indicated for use, under direct visualization, in surgical procedures, including minimally invasive cardiac surgery procedures." *Id.*

29. When a device is approved by the FDA for a general use, a specific indication for use can become a new intended use that requires submission of an additional 510(k) approval to establish the safety and effectiveness of the device. *See* Exhibit 3, p. 16-20, 24; *see also* Exhibit 3, p. 48 (FDA warning letter cautioning a company with 510(k) clearance for indicated use of a general procedure that it must discontinue its promotion of its device to treat a specific condition.)

30. Atrial fibrillation is a very fast and irregular beating of the atria. Atrial fibrillation is the most prevalent type of arrhythmia leading to hospital admission. Over 2.2 million Americans suffer from atrial fibrillation and approximately 160,000 new cases are found every year. *See* Exhibit 10, p. 89.

31. The FDA has determined that the use of Defendants' product to treat the condition of atrial fibrillation is a specific indication for a new intended use, which requires an additional pre-market approval, due to considerations of safety and effectiveness. *See* Exhibit 3, p. 24; Exhibit 9, p. 259; see also Exhibit 3, p. 39 (Article suggests that completion of a study is necessary to obtain FDA approval for the "specific atrial fibrillation indication.")

32. There is not yet an efficacy study assessing the safety and efficacy of using Defendants' product to treat the condition of atrial fibrillation. Defendants have not completed its on-going study, entitled RESOLVE-AF (Randomized Study of Surgical Ablation with Microwave Energy for the Treatment of Atrial Fibrillation). *See* Exhibit 3, p.42, 45; Exhibit 6, p. 30.

33. Defendants have not received FDA clearance or 510(k) approval supporting the specific use of microwave surgical ablation to treat the condition of atrial fibrillation. *See* Exhibit 4, p. 1; Exhibit 9, p. 148, 259-260.

34. The FDA has denied Defendants specific approval for the use of microwave surgical ablation to treat atrial fibrillation. *See* Exhibit 4, p. 1 (Atricure press release indicating that Boston Scientific, like Atricure, has been denied FDA clearance for the use of cardiac ablation tools to treat the condition of atrial fibrillation.)

35. The only functional use of Defendants' microwave surgical ablation system is to treat the condition of atrial fibrillation. For example, all 15 references to clinical studies provided in Defendants' "white papers," its statement of proposed policy, pertain to the

treatment of atrial fibrillation and there is not a single clinical study using the device on any condition other than atrial fibrillation. *See* Exhibit 3, p. 37.

36. Thus, all current uses of the microwave surgical ablation system are off-label. Moreover, the underlying purpose of all of Defendants' training and marketing of its microwave ablation system is to promote the off-label treatment of atrial fibrillation. *See* Exhibit 6, p. 2-40; Exhibit 10, p. 3-143

B. The Fraudulent Coding for Defendants' Microwave Surgical Ablation Procedure

37. Defendants solicit and induce hospitals to use an incorrect procedural code when using its product as a stand-alone procedure to obtain a 355% higher reimbursement amount from Medicare. This amounts to a $21,765 overcharge per procedure, aggregating to tens of millions of dollars a year in fraudulent billing paid by Medicare.

38. Defendants' promotional brochure entitled "Guidant Microwave Surgical Ablation: Hospital Reimbursement," (also available online (http://www.guidant.com/reimbursement/cs_codes/Micro_Ablation.pdf) instructs hospitals to designate treatment of atrial fibrillation with its product under "ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach)." Exhibit 5, p. 1. This is the wrong code to use. ICD-9 procedural code 37.33 designates the use of "open chest" approaches, including the Maze procedure. *See* Exhibit 5, p. 15, 16. Defendants' surgical ablation system, used as a stand-alone procedure, does not involve an open approach, and is in fact a minimally invasive percutaneous approach. *See* Exhibit 2, p. 1.

39. The correct and proper procedural code to use for Defendants' microwave surgical ablation system, when used as a stand-alone procedure, is 37.34 (excision or destruction

of other lesion or tissue of heart, other approach), which refers to use of a peripherally inserted catheter or use of another miniature instrument inserted percutaneously. *See* Exhibit 5, p. 16. The Medicare Diagnosis Related Group (DRG) associated with procedural code 37.34 is DRG 518, which provides a Medicare reimbursement of $8,524. Exhibit 5, p. 1, 22, 25. The DRG code associated with the procedural code 37.33, the code for open heart surgery, is DRG 108, which reimburses hospitals $30,289. *See* Exhibit 5, p. 1, 30. By promoting and encouraging the use of the wrong procedural code 37.33, which is designated for open heart surgery, Defendants deceive Medicare into reimbursing hospitals and doctors for an amount 355% higher than the amount of the correct code. The use of this incorrect code results in an over-reimbursement of approximately $21,765 [$30,289 minus $8,524] each time Defendants' microwave surgical ablation system is used as a stand-alone procedure.

40. The Defendants' brochure "Guidant Microwave Surgical Ablation: Hospital Reimbursement" points out that designation of microwave surgical ablation, as a stand-alone procedure, under DRG 108 will result in a $30,289 Medicare reimbursement and that: "Reimbursement for surgical ablation is higher than catheter ablation (DRG 518 = $8,524)." *See* Exhibit 5, p.1. The Defendants therefore promote their microwave ablation system to hospitals by instructing them that they can obtain a 355% higher reimbursement for the off-label use of Defendants' microwave surgical ablation system, as a stand-alone procedure, if they use an incorrect code associated with DRG 108 when filing claims for Medicare reimbursement.

41. Defendants also fraudulently promote the use of a nonexistent CPT code (current procedural terminology code), which it has induced hospitals to use when filing Medicare

claims for the use of Defendants' product to treat atrial fibrillation. The CPT codes are a listing of descriptive terms and identifying codes for reporting medical services. Defendants advise hospitals to use, CPT 33252. There is no listing for CPT 33252 in medical coding and compliance manuals, thus, it appears that the code does not exist. *See* Exhibit 6, p. 24.

42. Defendants' promotional materials provide a case study of the exceedingly over-priced reimbursement that a hospital in Illinois, stands to receive from Medicare by designating the incorrect codes, DRG 108 and procedural code procedural code 37.33, for the use of microwave surgical ablation as a stand-alone procedure. A slide in Defendants' marketing presentation entitled "[Redacted] Hospital Actual 2007 Medicare Reimbursement," which refers to Medicare reimbursement from October 2006 to September 2007, delineates that the hospitals will receive an actual Medicare reimbursement of $28,378, whereas, the cumulative cost of the entire procedure amounts to only $10,650. This $10,650 cost includes the average medical and procedural cost of ablation, Endo-Gia Stapler, purchase of the Flex 10 probe, three-hours use of the operating room, one-day placement in the Intensive Care Unit, two additional days hospital stay, and med-par costs. *See* Exhibit 6, p. 24. Thus, the remaining margin of profit from Medicare Reimbursements is $17, 728 per a stand-alone procedure. *Id.* If the hospital performs just one stand-alone procedure per month, the resulting profit from Medicare reimbursement is $212,736 per year. *See* Exhibit 6, p. 25.

43. Defendants' promotional materials regarding the hospital in Illinois also demonstrate that Defendants promote the use of the nonexistent CPT code 33252 for the use of their product in treating the condition of atrial fibrillation. *See* Exhibit 6, p. 24.

44. Defendants boast in their promotional materials that, across the country, there is an estimated seven billion dollars a year to be made by hospitals from Medicare part A reimbursements for the off-label treatment of atrial fibrillation. *See* Exhibit 6, p. 3.

45. Defendants also promote the off-label use of the microwave surgical ablation system by offering hospitals and doctors higher reimbursement amounts. Defendants' brochure, referenced above, refers to its instructions as an "economic map for hospitals treating patients with microwave surgical ablation" and discusses Medicare fiscal year 2006 payment rates. *See* Exhibit 5, p. 1. Defendants state, "CABG [which refers to an open-heart procedure] reimbursement increases approximately $4900 when performed concomitant with microwave surgical ablation." *Id.* Defendants, thus, advise hospitals that they can receive an average of $4,900 more from Medicare in CABG cases when they use Defendants' microwave surgical ablation system for the off-label use of treating atrial fibrillation, which is the only condition that can be treated with Defendants' procedure.

46. Relator and Defendants' other sales representatives and Ablation Account Managers were instructed that they should promote the off-label use of Defendants' microwave surgical ablation system to treat atrial fibrillation by advising hospitals and doctors that if they used (incorrect) codes, such as procedural code 37.33 and DRG 108 for the use of Defendants' product as a stand-alone procedure, they could obtain higher reimbursements from Medicare.

47. Defendants promote the off-label use of its product by reimbursing hospitals with kick-backs and remunerations such as rebates, lower prices, and free products, the proceeds of which are not reported or provided to Medicare, when the hospital agrees to

purchase a targeted quantity of the microwave ablation system to treat atrial fibrillation. *See* Exhibit 7.

48. Defendants provide hospitals with volume-based quarterly rebates for buying a targeted amount of Defendants' microwave surgical ablation system or for making a market share commitment to buy only Defendants' ablation products. *See* Exhibit 7, p. 4-5. These rebates are not reported to Medicare and the proceeds of the rebates are not passed on to Medicare.

49. Defendants provide discounted prices to hospitals that make quarterly market share commitments and agree to buy a minimum amount of Defendants' products. *See* Exhibit 7, p. 5. These price discounts are not reported to Medicare and the proceeds of the discounts are not passed on to Medicare. *See also* Exhibit 10, p. 75 (Sales representatives were trained to proposition hospitals by asking them: "Would you like to learn about a procedure with a large, untreated patient pool and favorable reimbursement?")

50. Defendants provide hospitals with free products, such as a generator valued at more than $30,000 if the hospital agrees to buy a targeted volume of Defendants' products. *See* Exhibit 7, p. 7. These free products are not reported to Medicare and Medicare is still charged for use of the generator.

51. Defendants offer bundling incentives to hospitals such that if a hospital buys three scopes, valued at $3,200 each, it will get one scope, for free. *See* Exhibit 7, p. 1, 7; Exhibit 10, p. 68, 75. The free scope is not reported to Medicare, and Medicare is instead charged for all four scopes.

52. Defendants' sales representatives also promote the off-label use of Defendants' product by directly training doctors to use Defendants' microwave surgical ablation system to treat atrial fibrillation. *See generally* Exhibit 10, p. 73, 76 (outlining the measures Sales Representatives are required to take to target and train new surgeons to use Defendant's MIS [minimally invasive surgery] procedure to treat atrial fibrillation). Relator received extensive instructions regarding her responsibility to train doctors to use Defendants' product off-label to treat atrial fibrillation, including a ten-day "New Hire Training" that focused on using the FLEX Microwave Ablation System to treat atrial fibrillation. During this training, Ms. George and other new hires were introduced to the Maze procedure and other common techniques to treat atrial fibrillation, and then shown how use of microwave surgical ablation was a superior technique. New hires were not taught to treat any conditions, other than atrial fibrillation, with Defendants' product. Among the instructional materials that Ms. George received during the new hire training was a document that outlines the "seven basic steps" for using the Flex 10 procedure to treat atrial fibrillation, including the methods of routing, positioning, and applying lesion sets used during the procedure. Prior to finishing the training, Ms. George was required to demonstrate to corporate trainers at Boston Scientific that she could "teach" proper lesion sets and surgical technique using Defendants' product to treat the condition of atrial fibrillation.

53. Relator and Defendants' other sales representatives were required to accompany surgeons into the operating room to provide surgeons with detailed instructions regarding how they could administer Defendants' product off-label to treat Medicare patients with atrial fibrillation.

54. Defendants have other employees entitled "Ablation Account Managers" who focus entirely on training surgeons to perform microwave surgical ablation to treat atrial fibrillation. These Ablation Account Managers are required to accompany the surgeons into the operating room the first three times they perform microwave surgical ablation to provide the surgeon with detailed surgical techniques on how to treat atrial fibrillation with microwave surgical ablation.

55. Defendants provide grants to surgeons that promote its procedures. These grants are used to fund the training of new surgeons to use Defendants' product off-label to treat the condition of atrial fibrillation. *See* Exhibit 10, p. 79-83; *see also* Exhibit 6, p. 28.

56. Defendants also provides free advertising services for surgeons that promote its procedure by paying for the design, publication, and marketing of brochures, including camera-ready art work, that advertise the surgeon's name and explain that the surgeon treats atrial fibrillation by using Defendants' microwave surgical ablation system. *See* Exhibit 6, p. 31.

57. Defendants' marketing presentations list 11 surgeons that are provided with grants, brochures, and other incentives to promote the off-label use of Defendants' product: Dr. Balkhy, Dr. Jansens, Dr. Kshettry, Dr. Srivastava, Dr. Pruitt, Dr. Masoor, Dr. Maessen, Dr. Williams, Dr. Molloy, Dr. Poa, and Dr. Saltman. *See* Exhibit 6, p. 32-40.

VI. SPECIFIC CASES OF FRAUDULENT CLAIMS SUBMITTED TO MEDICARE FOR THE OFF-LABEL TREATMENT OF ATRIAL FIBRILLATION

58. Patient A [to maintain privacy of individual patients, they are not identified by name], a resident of Indiana, was diagnosed with permanent atrial fibrillation. On October 25, 2006, Dr. Beckman at Methodist hospital treated Patient A and administered

Defendants' microwave surgical ablation, as a stand-alone procedure to treat Patient A's atrial fibrillation. A number of Defendants' Sales Representatives, Ablation Account Managers, and other surgeons accompanied Dr. Beckman into the operating room to observe the use of Defendants' microwave surgical system to treat Patient A's atrial fibrillation. This was a Boston Scientific sponsored training course paid for by the company.

59. Upon completion of the procedure, the Methodist Hospital filed a claim for Medicare reimbursement and used the ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach) and the related DRG code 108, which allowed the hospital to receive a reimbursement of approximately $30,000 for a stand-alone use of Defendants' microwave ablation system, which is a minimally invasive procedure.

60. Patient B, a resident of Indiana, was diagnosed with permanent atrial fibrillation. On October 11, 2006. Dr. Beckman at Methodist Hospital treated Patient B and administered Defendants' microwave surgical ablation, as a stand-alone procedure to treat Patient B's atrial fibrillation. A number of Defendants' Sales Representatives, Ablation Account Managers, and other surgeons accompanied Dr. Beckman into the operating room to observe the use of Defendants' microwave surgical system to treat Patient B's atrial fibrillation. This was a Boston Scientific sponsored training course paid for by the company.

61. Upon completion of the procedure, Methodist Hospital filed a claim for Medicare reimbursement for Patient B and entered the ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach) and the related DRG code

108, which allowed the hospital to receive a reimbursement of approximately $30,000 for a stand-alone use of Defendants' microwave ablation system, which is a minimally invasive procedure.

62. Patient C, a resident of Indiana, was diagnosed with permanent atrial fibrillation. On September 28, Dr. Beckman at Methodist Hospital treated Patient C and administered Defendants' microwave surgical ablation, as a stand-alone procedure to treat Patient C's atrial fibrillation. A number of Defendants' Sales Representatives, Ablation Account Managers, and other surgeons accompanied Dr. Beckman into the operating room to observe the use of Defendants' microwave surgical system to treat Patient C's atrial fibrillation. This was a Boston Scientific sponsored training course paid for by the company.

63. Upon completion of the procedure, Methodist Hospital filed a claim for Medicare reimbursement for Patient C and entered the ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach) and the related DRG code 108, which allowed the hospital to receive a reimbursement of $30,000 for a stand-alone use of Defendants' microwave ablation system, which is a minimally invasive procedure.

64. Patient D, a resident of Wisconsin, was diagnosed with permanent atrial fibrillation. On September 6th, 2006, Dr. Balkhy at University of Milwaukee Medical Center treated Patient D and administered Defendants' microwave surgical ablation, as a stand-alone procedure to treat Patient D's atrial fibrillation. A number of Defendants' Sales Representatives, Ablation Account Managers, and other surgeons accompanied Dr. Balkhy into the operating room to observe the use of Defendants' microwave surgical

system to treat Patient D's atrial fibrillation. This was a Boston Scientific sponsored training course paid for by the company.

65. Upon completion of the procedure, the University of Milwaukee Medical Center filed a claim for Medicare reimbursement for Patient D and entered the ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach) and the related DRG code 108, which allowed the hospital to receive a reimbursement of $30,000 for a stand-alone use of Defendants' microwave ablation system, which is a minimally invasive procedure.

VI. CLAIMS FOR RELIEF

COUNT ONE

31 U.S.C. § 3729(a)(1):

CAUSING FALSE OR FRAUDULENT CLAIMS FOR PAYMENT TO BE PRESENTED TO THE GOVERNMENT

66. Relator realleges and reincorporate all preceding 65 paragraphs of the Complaint as the initial paragraph of this Count I.

67. The False Claims Act, 31 U.S.C. § 3729 et seq., prohibits anyone from, among other things, causing a false or fraudulent claim for payment to be presented to the United States Government.

68. From approximately 2001 through to the present, in the Northern District of Illinois, and elsewhere throughout the United States, Defendants caused the submission of false claims to Medicare by inducing health care providers to use incorrectly assigned procedural codes when billing for treatments to patients. *See* Exhibit 8 (Advertisement

from 2005 indicates that Defendants' product has been marketed since 2001).

69. Defendants have solicited and induced health care providers to use an incorrect ICD-9 procedural code for the stand-alone-use of its microwave ablation system to fraudulently over-price and maximize Medicare reimbursement.

70. Defendants' act of knowingly causing the submission of false claims with incorrectly-assigned ICD-9 codes resulted in an over-reimbursement of approximately $21,765 each time Defendants' microwave surgical ablation system was used as a stand-alone product.

71. Defendants misuse of the ICD-9 code also permits reimbursement for the off-label use of its product for treatments of atrial fibrillation, for which Medicare would otherwise deny reimbursement.

72. To be eligible for reimbursement from Medicare, a medical device must be used for a "medically accepted indication."

73. The only practical function of Defendants' product is to treat atrial fibrillation, which is not a "medically accepted indication" for its product.

74. Defendants have promoted the use of its product to treat atrial fibrillation by training surgeons to use its product for the off-label treatment of atrial fibrillation.

75. Defendants have also promoted the off-label use of its product by requiring its sales representatives and Ablation Account Managers to accompany surgeons into the operating room to provide detailed surgical instructions to the use of Defendants' product to treat atrial fibrillation. Ablation Account Managers were required to accompany new surgeons into the operating room for their first three cases to treat atrial fibrillation.

76. Defendants have further promoted the off-label use of their product by giving rebates, price reductions, and free products to hospitals that purchased a targeted volume of Defendants' product for off-label treatments and the proceeds of those kick-backs were not reported or passed on to Medicare. The hospital thereupon included the entire price of device in its Medicare reimbursement request and was reimbursed for said full price, which was more than it was entitled to recover.

77. Defendants have, additionally, provided grants to surgeons to promote the off-label use of their procedures. These grants are used to fund the training of new surgeons to use Defendants' product off-label to treat the condition of atrial fibrillation.

78. Defendants' off-label promotion of its product to treat atrial fibrillation has caused the submission of false claims for reimbursement from Medicare for the off-label use of Defendants' product to treat atrial fibrillation.

79. As a result of Defendants' fraudulent conduct, the United States Government has spent millions of dollars more in reimbursements for Defendants' microwave ablation systems than it should have paid had the procedures been billed correctly and properly.

COUNT TWO

31 U.S.C. § 3729 (a):

FALSE STATEMENTS USED TO GET FALSE CLAIMS PAID

80. Relator realleges and reincorporate all preceding 79 paragraphs of the Complaint as the initial paragraph of this Count II.

81. From approximately 2001 through to the present, in the Northern District of Illinois and elsewhere throughout the United States, Defendants knowingly caused to be made or used a false record or statement to get a false or fraudulent claim paid or

approved by the Government. *See* Exhibit 8 (Advertisement from 2005 indicates that Defendants' product has been marketed since 2001).

82. Defendants caused false records or statements to be made or used by instructing and inducing health care providers to use incorrect ICD-9 procedural codes when submitting Medicare claims for the stand-alone use of Defendants' product, which resulted in an over-reimbursement of approximately $21,765 each time Defendants' microwave surgical ablation system was used as a stand-alone product.

COUNT THREE

31 U.S.C. § 3729 (a)(3):

FALSE CLAIMS ACT CONSPIRACY

83. Relator realleges and reincorporate all preceding 82 paragraphs of the Complaint as the initial paragraph of this Count III.

84. From approximately 2001 through to the present, in the Northern District of Illinois, and elsewhere throughout the United States, the Defendants together with others known and unknown violated the False Claims Act by conspiring to knowingly and willfully causing the submission of false claims for reimbursement from Medicare. *See* Exhibit 8 (Advertisement from 2005 indicates that Defendants' product has been marketed since 2001).

85. It was a part of this conspiracy that Defendants and its co-conspirators knowingly and willfully submitted false claims to Medicare by using incorrect ICD-9 procedural codes, which resulted in an over-reimbursement of approximately $21,765 each time Defendants' microwave surgical ablation system was used as a stand-alone product.

86. It was further a part of the conspiracy that Defendants and its co-conspirators

knowingly and willfully made material false statements to Medicare by concealing the fact that rebates, price reductions, and free products were given to hospitals that purchased a targeted volume of Defendants' product for off-label treatments and the proceeds of those kick-backs were not reported or passed on to Medicare. The hospital thereupon included the entire price of device in its Medicare reimbursement request and was reimbursed for said full price, which was more than it was entitled to recover.

87. It was further a part of the conspiracy that Defendants and its co-conspirators knowingly and willfully made material false statements in their submissions of claims to Medicare by concealing the fact that Defendants' product was used for the off-label purpose of treating atrial fibrillation.

88. Through the acts described above and otherwise, Defendants entered into a conspiracy or conspiracies among themselves and with others to defraud the United States Medicare program by getting false and fraudulent claims allowed or paid.

COUNT FOUR

31 U.S.C. § 3729(a)(7):

KNOWINGLY MAKING OR USING A FALSE STATEMENT TO AVOID OR CONCEAL OBLIGATIONS

89. Relator realleges and incorporates herein by reference each and every allegation set forth in paragraphs 1 through 88.

90. From approximately 2001 through to the present in the Northern District of Illinois, and elsewhere throughout the United States, Defendants knowingly made and

used false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Government. *See* Exhibit 8 (Advertisement from 2005 indicates that Defendants' product has been marketed since 2001).

91. Defendants knowingly and willfully made material false statements to Medicare by concealing the fact that rebates, price reductions, and free products were given to hospitals that purchased a targeted volume of Defendants' product for off-label treatments, and the proceeds of those kick-backs were not reported or passed on to Medicare. The hospital thereupon included the entire price of device in its Medicare reimbursement request and the hospital was reimbursed for the full price, which was more than it was entitled to recover. Defendants caused hospitals to conceal this obligation to induce hospitals to purchase a higher volume of its product for the off-label treatment of atrial fibrillation.

VII. PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment against Defendants as follows:

92. That Defendants cease and desist from violating the False Claims Act, including 31 U.S.C. §3729(a)(1), 31 U.S.C. §3729(a)(3), and 31 U.S.C. §3729(a)(7);

93. That this Court enter judgment against the Defendants in an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 31 U.S.C. §3729 et seq;

94. That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. §3730(d) of the False Claims Act;

95. That Relator be awarded all costs and expenses of this action, including attorneys' fees;

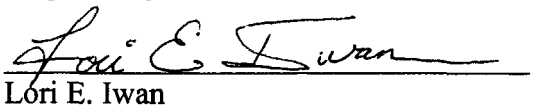
96. That Relator recover such other relief as the Court deems just and proper.

VIII. JURY DEMANDED

97. Relator respectfully requests a trial by jury as to all issues.

Dated: November 9, 2006

Respectfully submitted:



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